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(54) Title: END-SIDE ANASTOMOSIS SYSTEMS

(57) Abstract: End-side anastomosis fittings are described herein. The fittings may be deployed over a guidewire, in a sheath or by applying side-to-side force and feeding the fitting through an opening in a host vessel wall. When a fitting as described is deployed within a host vessel, the exterior surface of the leading petal contacts the interior surface of the host vessel. A deflectable rear petal anchors the fitting within the host vessel once it is advanced through the host vessel wall. Additional petals that may be included provide more complete contact. Support devices usable with the fittings secure a fitting to a host vessel and prevent blood leakage between the opening through the host vessel wall and the base of the end-side fitting. The support device selected may include funnel features designed to relieve stress on a graft attached to the fitting.

END-SIDE ANASTOMOSIS SYSTEMS

CROSS-REFERENCE TO RELATED APPLICATIONS

This application claims the benefit of priority to U.S. Provisional Patent Application Serial No. 60/169,104, entitled "Improved Anastomosis Systems", filed December 6, 1999 and U.S. Provisional Patent Application Serial No. 60/178,822, entitled "Advanced Anastomosis Systems", filed January 28, 2000.

FIELD OF THE INVENTION

This invention relates to devices for deploying and securing the ends of bypass grafts designed to provide a fluid flow passage between at least two host vessel regions (or other tubular structure regions). More particularly, the invention relates to bypass grafts that are secured at target host vessel locations thereby producing a fluid flow passage from the first host vessel location through the bypass graft and to the second host vessel location. The invention describes sutureless anastomosis systems that do not require cardiopulmonary bypass support when treating coronary artery disease.

BACKGROUND OF THE INVENTION

Current techniques for producing anastomoses during coronary artery bypass grafting procedures involve placing the patient on cardiopulmonary bypass support, arresting the heart, and interrupting blood flow to suture, clip, or staple a bypass graft to the coronary artery and aorta. However, cardiopulmonary bypass support is associated with substantial morbidity and mortality.

This invention provides devices and methods to position and secure bypass grafts at host vessel locations without having to stop or re-route blood flow. Accordingly, this invention does not require cardiopulmonary bypass support and arresting the heart while producing anastomoses to the coronary arteries. In addition, this invention mitigates risks associated with suturing, clipping, or stapling the bypass graft to the host vessel(s); namely, bleeding at the attachment sites and collapsing of the vessel around the incision point. The anastomoses of the invention meet the need of being able withstand the pressure exerted by the pumping heart and ensure blood does not leak from the anastomoses into the thoracic cavity, abdominal cavity, or other region exterior to the vessel wall.

SUMMARY OF THE INVENTION

The invention addresses vascular bypass graft treatment regimens requiring end-side anastomoses to attach bypass grafts to host vessels. The scope of the invention includes improvements to the systems used to position and secure bypass grafts for treating vascular diseases such as atherosclerosis, arteriosclerosis, fistulas, aneurysms, occlusions, thromboses, and the like. The improvements to the bypass grafts and delivery systems of this invention also aid in attaching the ends of ligated vessels, replacing vessels harvested for bypass grafting procedures (e.g. radial artery), and re-establishing blood flow to branching vessels which would otherwise be occluded during surgical grafting procedures (e.g. the renal arteries during abdominal aortic aneurysm treatment). In addition, the invention addresses other applications such as, but not limited to, producing arterial to venous shunts for hemodialysis patients, bypassing lesions and scar tissue located in the fallopian tubes causing infertility, attaching the ureter to the kidneys during transplants, and treating gastrointestinal defects (e.g. occlusions, ulcers, obstructions, etc.).

This invention provides improvements to the sutureless anastomosis systems that enable a physician to quickly and accurately secure a bypass graft to a host vessel or other tubular body structure. The delivery systems of the invention do not require stopping or re-routing blood flow while producing the anastomosis; current techniques require interrupting blood flow to suture, clip, or staple a bypass graft to the host vessel wall.

The fittings of the invention are intended to secure biological bypass grafts, obtained by harvesting vessels from the patient or another donor patient, or synthetic bypass graft materials to a patient's host vessel. When using harvested vessels, the fitting embodiments must accommodate a variety of harvested vessel sizes and wall thicknesses. When using synthetic bypass graft materials, the fittings may be incorporated in the bypass graft design to eliminate the step of attaching the bypass graft to the fitting prior to deploying the bypass graft and fitting.

One aspect of the invention provides improved fitting embodiments designed to compress into a reduced diameter while attaching the bypass graft to the fitting and/or deploying the fitting through the delivery system. Once deployed, the compressible fittings of the invention expand towards their preformed geometry such that they exert radial force at the vessel attachment sites; this helps maintain the patency of the anastomosis.

An aspect of the invention includes angled fittings designed to produce anastomoses between bypass grafts and host vessels such that the angle between the bypass graft and the host vessel reduces turbulent flow near the anastomosis. The angled fittings may also be designed compressible.

Sheathless anastomosis embodiments are disclosed which are designed to insert the petals or securing end of the end-side fitting into the host vessel without having to insert the fitting through a deployment sheath.

Further features and advantages of the inventions will be elaborated in the detailed description and accompanying drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

Figures 1A to 1F show an end-side fitting capable of being deployed over a guidewire and the deployment steps to position and secure the end-side fitting.

Figures 2A to 2C show support device embodiments.

Figures 3A and 3B show a slotted support device having a funneled proximal end.

Figure 3C shows a reinforcing structure to secure the support device of Figures 3A and 3B.

Figure 4 shows a support device having a partially slotted side and a funneled proximal end.

Figure 5 shows a curved support device having a funneled proximal end.

Figure 6A shows a side view of a dilating end-side fitting.

Figure 6B shows a top view of the dilating end-side fitting of Figure 6A.

Figure 6C shows a cross-sectional view of the dilating end-side fitting of Figure 6A taken along the line A-A.

Figure 6D shows a top view of a dilating end-side fitting in response to external forces (C).

Figure 6E shows a cross-sectional view of the dilating end-side fitting of Figure 6D taken along the line B-B.

Figure 7A shows a bottom view of a dilating end-side fitting in a flattened configuration.

Figure 7B shows a bottom view of a dilating end-side configured for host vessels having a relatively large diameter compared with the diameter of the bypass graft.

Figure 7C shows a top view of a dilating end-side configured for host vessels having a relatively medium or small diameter of the present invention.

Figure 7D shows a bottom view of the dilating end-side fitting of Figures 7B or 7C configured for introduction through an opening into a host vessel.

Figures 8A and 8B show a bottom view and a top view of the front piece of a two piece dilating end-side fitting.

Figures 8C and 8D show a side view and a top view of the rear piece of a two piece dilating end-side fitting.

Figure 9A shows a side view of an introducer configured to advance the petals of a dilating end-side fitting through an opening into a host vessel.

Figure 9B shows a bottom view of the introducer of Figure 9A.

Figure 9C shows a top view of the introducer of Figure 9A.

Figure 9D shows a bottom view of the introducer of Figure 9A with the petals of a dilating end-side fitting positioned within the introducer.

Figure 9E shows a side view of the introducer of Figure 9A with the petals of a dilating end-side fitting positioned within the introducer.

DETAILED DESCRIPTION OF THE INVENTION

The fittings and deployment systems of the present invention are intended to produce anastomoses between bypass grafts and host vessels to treat vascular abnormalities such as stenoses, thromboses, other occlusions, aneurysms, fistulas, or other indications requiring a bypass graft. The systems of the present invention are also useful in bypassing stented vessels that have restenosed, and saphenous

vein bypass grafts that have thrombosed or stenosed. Current approaches for treating stenosed stents have not been successful at safely and reliably removing the lesion and opening the vessel lumen. Therefore, the approach described by this invention, which produces a blood flow conduit around the stented lesion, mitigates concerns associated with damaging the stent or forming emboli while removing deposits attached to the stent. The same argument holds true for saphenous vein grafts that have restenosed or thrombosed.

The inventive fitting embodiments discussed herein are directly amenable to robotic surgery and less invasive (i.e. minimally invasive) surgery involving a thoracostomy or mini median sternotomy to access the anastomosis site. In particular, the fittings of the present invention enable automation of the attachment of the bypass graft to the fitting, especially when considering the use of the end-side fittings capable of being advanced over a guidewire as described below.

The present invention includes end-side fitting embodiments having specific characteristics so that they may be inserted through a small puncture without the need for a deployment sheath. Figures 1A to 1F shows a system for inserting an end-side fitting 2 without requiring the use of a deployment sheath. A guidewire 4 is inserted through the host vessel 6 wall and into the host vessel interior. The end-side fitting has a distal hole or aperture 8 to pass over the guidewire and a proximal hole or aperture 10 that also accepts the guidewire. The distal hole 8 provides a smooth transition from the guidewire 4 to the leading petal 12 of the end-side fitting to readily advance the leading petal through the opening in the host vessel wall. The leading petal 12 has a smooth transition to the base 14 of the end-side fitting to dilate the opening while the end-side fitting is advanced over the guidewire and through the host vessel wall opening. The cross-section (not shown) of the leading petal 12 is an arc having a radius of curvature that approximates the radius of curvature of the host vessel 6. Thus, when the end-side fitting is completely inside the host vessel, the exterior surface of the leading petal contacts the interior surface of the host vessel. The leading petal 12 may be slightly squeezed together (by hand or using clamps or the like) to produce a better transition from the guidewire to the base 14 of the fitting. Once the end-side

fitting 2 is advanced until the base 14 of the fitting resides approximate the opening through the host vessel wall, the rear petal 16 must be advanced through the opening. As shown in Figures 1C and 1D, the rear petal 16 can be deflected towards the base 14 of the end-side fitting using the guidewire or due to the force exerted by the host vessel wall as the proximal end of the end-side fitting is advanced through the host vessel wall. The rear petal 16 is designed so it is capable of bending towards the base of the fitting but is unable to readily deflect towards the leading petal 12. This anchors the end-side fitting inside the host vessel once the rear petal 16 is advanced through the host vessel wall. Preferably, the length of the rear petal 16 is less than the diameter of the host vessel and is positioned so the rear petal 16 may be advanced through the opening without the leading petal 12 or base of the fitting having to deform the posterior surface of the host vessel. As shown in Figure 1F, once positioned entirely through the host vessel wall, a support device 18 is used to lock the end-side fitting inside the host vessel 6 and prevent blood leakage between the opening through the host vessel wall and the base 14 of the end-side fitting. Tabs 20 anchor the support device 18 in place, compressing the host vessel wall against the leading petal 12 and rear petal 16 of the end-side fitting.

As a result of the sheathless deployment process, these end-side fittings may be fabricated using any biocompatible material (e.g. nickel titanium, PET, PTFE, urethane, silicone, polyester, etc.) or their composites via manufacturing processes such as injection molding, blow molding, dipping, etc. In addition, this mitigates concerns of maximum strain imposed on the petals (when made of certain materials) when compressing the end-side fitting into a reduced diameter for advancing through a deployment sheath.

The end-side fittings of the present invention are preferably constructed from a metal (e.g., titanium), alloy (e.g., stainless steel or nickel titanium), thermoplastic (e.g., PTFE), thermoset plastic (e.g., polyethylene terephthalate, or polyester), silicone or combination of the aforementioned materials into a composite structure; other materials may alternatively be used. For example, end-side fittings fabricated from nickel titanium may be clad with expanded PTFE,

polyester, PET, or other material that may have a woven or porous surface. The fittings may be coated with materials such as paralyne or other hydrophilic substrates that are biologically inert and reduce the surface friction. To further reduce the surface tension, metallic or metallic alloy fittings may be electropolished. Evidence suggests that electropolishing reduces platelet adhesion because of the smooth surface. Alternatively, the fittings may be coated with heparin, thromboresistance substances (e.g., glycoprotein IIb/IIIa inhibitors), antiproliferative substances (e.g., rapamycin), or other coatings designed to prevent thrombosis, hyperplasia, or platelet congregation around the attachment point between the bypass graft and the host vessel. Alternatively, a material such as platinum, gold, tantalum, tin, tin-indium, zirconium, zirconium alloy, zirconium oxide, zirconium nitrate, phosphatidyl-choline, or other material, may be deposited onto the fitting surface using electroplating, sputtering vacuum evaporation, ion assisted beam deposition, vapor deposition, silver doping, boronation techniques, a salt bath, or other coating process. A still further improvement of the fittings is to include beta or gamma radiation sources on the end-side fittings. A beta or gamma source isotope having an average half-life of approximately 15 days such as Phosphorous 32 or Paladium 103 may be placed on the base and/or petals of the end-side fitting using an ion-implantation process, chemical adhesion process, or other suitable method.

As shown in Figure 1F, after positioning the end-side fitting inside the vessel such that the base of the fitting extends through the opening into the host vessel wall and the petals contact the interior surface of the host vessel, the support device **18** is positioned over the base **14** of the fitting and locked in place. The end-side fittings may incorporate tabs **20**, threads (not shown), or other locking mechanism with which to secure a support device **18** to the end-side fitting. Tabs **20** are preformed so they protrude radially from the base of the fitting to provide a mechanism to secure the support device, once positioned distal to the tabs. The tabs are also preferably fabricated from a memory elastic material to incorporate a spring characteristic permitting the tabs to be compressed into a reduced diameter during deployment. Of course, the tabs do not need to be fabricated from memory

elastic materials in the case when they do not need to be compressed into a reduced diameter during introduction. The tabs in the illustrated embodiment are compressed to facilitate inserting the base of the fitting through the delivery system and expand towards their preformed configuration once the fitting is positioned and the external force compressing the tabs is removed. The tabs are fabricated by creating the desired pattern in the fitting material by laser drilling, chemical etching, EDM, or other manufacturing process, whether fitting is fabricated as a sheet or tube. Alternatively, tabs may be fabricated as a separate component and bonded to the fitting by spot welding, laser welding or other suitable manufacturing process.

The support device **18** is alternatively locked to the base of the fitting using adhesives, implantable clips, staples, sutures, or other attachment means. The support device of the illustrated embodiment incorporates an outer compliant covering designed to produce a blood-tight seal and prevent damaging the vessel wall by excess compression. The support device also incorporates an encapsulated central memory elastic core used to maintain the position of the support device relative to the vessel wall and prevent permanent deformation of the support device when expanded into an enlarged diameter for positioning around the base of the fitting. The support device is preferably fabricated as a coil with approximately 1 turn. This support device produces a side-opening upon expansion, which permits advancing the support device over the side of the end-side fitting base **14** or the side of the bypass graft **22**. This eliminates the need to preload the support device over the bypass graft. The expandable/compressible support device is also capable of producing a secure, blood tight interface between host vessel walls and the petals of end-side fittings having a compressible / expandable base for tailoring the outer diameter of the base to match the size of the bypass graft.

The support device may alternatively be constructed from polymers such as polypolyethylene, polycarbonate, PEEK, silicone, nickel titanium, spring stainless steel, other alloy, combination of the aforementioned materials, or other material that may be extruded, injection molded, rolled, or otherwise formed into a tube

having the desired cross-sectional profile. In addition, the support device may incorporate a braided, woven, or wound layer laminated between two polymer layers to resist kinking and improve the column strength and torque response. Alternatively, the support device may be fabricated with a memory elastic central layer encapsulated with a compliant covering. The support device preferably has porosity sufficient to permit air to diffuse into tissue covered by the support device. The pore size may be as high as approximately 100 μm as long as the porosity is chosen such that blood does not continually leak through the support device. If the pore size is chosen such that it completely restricts blood flow even when the porosity is extremely high then the pore size needs to be less than approximately 8 μm.

Figures 2A to 2C show additional support device 18 embodiments. Of particular note, the curvature of the support devices shown in Figures 2A and 2C depends on the radius of curvature for the host vessel. It is prefered that the curvature generally match that of the host vessel to ensure adequate hemostasis at the anastomosis and contact between the support device 18 and the host vessel 6 wall.

An alternative support device is shown in Figures 3A and 3B. This support device 18 has a distal flared end 24 to improve the hemostasis of the end-side fitting, a base that contains notches 26 to accept retaining clips for securing to the fitting base 14, a slot 28 through one side to permit advancing over the side of the fitting base, and a proximal funneled end 30 to improve the compliance and/or blood flow profile transition from the anastomosis to the body of the bypass graft. The retaining clip 32 shown in Figure 3C may be used to secure the support device to the base of the end-side fitting. The distal and proximal rings 34 of the retaining clip 32 fit inside the notches 26 of the support device 18 to prevent axial movement of the retaining clip and support device from the base of the fitting.

Figure 4 shows another support device 18 with a distal flared end 24, a slot 28 to permit advancing over the side of the fitting base 14, and a funneled proximal end 30 to transition from the anastomosis to the bypass graft and provide a strain relief to prevent kinking of the bypass graft. Funneled support devices

prevent dramatic overexpansion of the bypass graft, improving the transition from the anastomosis to the body of the bypass graft. This transition is particularly important when using harvested vessels such as the saphenous vein as the bypass graft.

When exposed to arterial blood pressure, saphenous veins tend to balloon, producing turbulent flow at the anastomosis. This may lead to hyperplasia or other unwanted physiologic abnormalities. By creating a smooth transition in diameter and stiffness, the flow profile is improved and the risks associated with compliance mismatch are substantially mitigated.

Support devices that have a slot 28 to permit advancing over the side of the fitting base or the side 14 of the bypass graft 22 may incorporate a latching mechanism to lock the edges that define the slot 28 together. This eliminates the need to use another locking mechanism such as a retaining clip, suture, implantable clips, staples, or other device.

Figure 5 shows an alternative support device 18 that has a curved proximal end 30 to provide a strain relief, produce a smooth transition from the anastomosis to the body of the bypass graft, and direct the blood flow through the bypass graft along a predetermined curve.

In addition to there being variations on the support devices described herein, there are still more end-side fittings 2 having specific characteristics to be inserted through a small puncture without the need for a deployment sheath. Figures 6A to 6E and Figures 7A to 7D show other dilating end-side fittings 2 that meet these requirements. The dilating end-side fittings 2 may incorporate a feature that enables following a guiding mechanism (e.g., guidewire, needle, or small dilator) directing the dilating end-side fitting into the host vessel interior and expand an opening through a host vessel wall.

End-side fitting embodiments may be fabricated from a tube of material having a desired cross-sectional geometry. The desired pattern of petals, tabs, holes, slots, and spaces may be fabricated on the tubular metal material and may be formed using chemical etching, electron discharge machining (EDM), laser cutting, or other manufacturing process. These end-side fittings may be

maintained as a complete tube or may be fabricated to incorporate a gap between opposite sides to make the fitting compressible and expandable, as will be discussed below.

Alternatively, the end-side fitting embodiments may be fabricated from a sheet of material cut into the desired pattern and formed (e.g., through an annealing process) into the desired cross-sectional geometry (circular, elliptical, or other shape), as shown in Figures 7A to 7C. The sides of the fitting may be bonded to form an enclosed tube or may be formed with a gap 36 between opposite sides to enable compressing the fitting into a reduced diameter for positioning the bypass graft over the base of the fitting and inserting the fitting through an opening into a host vessel having a diameter less than the expanded diameter of the fitting. Such compressible fittings also facilitate sizing issues since they accommodate a wide range of bypass graft sizes.

To produce these end-side fittings, the raw material may be fabricated into the desired pattern by chemically etching, EDM, laser cutting, or other manufacturing process. End-side fittings fabricated from sheet stock are then wrapped around mandrels having the desired resting cross-sectional profile(s) and the end-side fitting is heated until it assumes this configuration. If the sides are to be bonded, spot welding, laser welding, or other manufacturing process may be employed.

Figures 6A to 6E show a dilating end-side fitting that, like the fitting of Figures 2A-2F, does not require the use of a deployment sheath for insertion into a host vessel 6. As previously discussed, a guidewire may be inserted through the host vessel wall and into the host vessel interior, and the end-side fitting may or may not be capable of advancing over a guidewire (not shown). Regardless, the leading petal 12 of the fitting provides a smooth transition from the opening into the host vessel along the leading petal of the end-side fitting to readily advance the leading petal 12 through the opening in the host vessel wall. The leading petal 12 has a smooth transition to the base 14 of the end-side fitting 2 to dilate the opening while the end-side fitting is advanced through the host vessel wall opening. The leading petal 12 also incorporates links 38 that define spaces 40 throughout the

leading petal 12. The spaces 40 minimize the amount of foreign material exposed to blood flow and the links 38 permit compressing the leading petal into a reduced cross-section for insertion through an opening through the host vessel wall. The cross-section of the leading petal 12 (shown in Figure 6C) is an arc having a radius of curvature to approximate the radius of curvature of the host vessel in the fittings resting configuration. Thus, when the end-side fitting is advanced completely inside the host vessel, the exterior surface of the leading petal contacts the interior surface of the host vessel and provides a structure to secure the fitting to the host vessel wall. The leading petal 12 may be slightly compressed together (by hand or using clamps) as shown in Figures 6D and 6E to produce a better transition for insertion through an opening in the host vessel wall; this also improves the transition from the leading petal to the base of the fitting and prevents scraping the side of the host vessel wall during insertion (especially when inserting the end-side fitting into a host vessel having a small or medium size diameter.

Once the end-side fitting is advanced until the base 14 of the fitting resides approximate the opening through the host vessel wall, the rear petal 16 must be advanced through the opening. The rear petal 16 may be deflected towards the base 14 of the end-side fitting using the guidewire, clamp, or due to the force exerted by the host vessel wall as the proximal end of the end-side fitting is advanced through the host vessel wall. This rear petal is designed so it is capable of bending towards the base of the fitting but is unable to readily deflect towards the leading petal 12. Alternatively, as shown in Figures 7A to 7D, the rear petal may be fabricated such that it readily deflects forward toward the leading petal. This is especially useful when a guidewire may be used to compress the rear petal toward the leading petal while inserting the end-side fitting through an opening into the host vessel wall, as previously discussed. The rear petal 16 further anchors the end-side fitting inside the host vessel. In the preferred embodiment, the length of the rear petal 16 is less than the diameter of the host vessel and is positioned so the rear petal 16 may be advanced through the opening without the leading petal 12 or base of the fitting having to deform the posterior surface of the host vessel. Once positioned entirely through the host vessel wall, a support

device is used to lock the end-side fitting inside the host vessel and prevent blood leakage between the opening through the host vessel wall and the base 14 of the end-side fitting.

To facilitate deployment of the dilating end-side fitting, the rear petal 16 may be fabricated as a separate component from the fitting, as shown in Figures 8A to 8D. This separate rear petal member 42 is capable of locking to the distal leading component after the fitting is positioned through an opening in the host vessel wall and the rear petal is positioned appropriately. As shown in Figure 8A, the stem or base 14 of the fitting incorporates at least one slot 44 for the rear petal member 42 to slide into. The end-side fitting also incorporates a leading petal 12, side petals 46 that may or may not compress during insertion, holes 40 through the leading and side petals, relief cuts 48 defining extensions 50 that enhance hemostasis at the anastomosis, and a base or stem 14 for securing the bypass graft and maintaining the patency of the opening through the host vessel wall. Once the leading petal 12 and the side petals 46 of the fitting are inserting into the host vessel interior, the rear petal is advanced through the slot 44 in the base or stem 14 of the fitting and is secured to the base or stem of the fitting using a locking mechanism 52. The rear petal may also include holes to improve flexibility of the petal and promote cellular growth.

In the fitting embodiment shown in Figures 7A to 7D, an oval hole 40 in the leading petal 12 is adapted to follow a guidewire 4 previously inserted through the host vessel wall and into the lumen, as shown in Figure 7D. The guidewire 4 (or other mechanism as previously described), inserted through the host vessel wall, is inserted through the oval hole 40 such that when the end-side fitting is angled, the distal tip of the leading petal 12 follows the surface of the guidewire. This produces a smooth transition from the guidewire to the leading petal 12. As the end-side fitting is advanced, the leading petal expands the opening through the vessel wall.

The side petals 46, as shown in Figure 7D, are maintained in a compressed configuration for the expansion of the opening and deployment through the host vessel wall. A guidewire 4 may be inserted through at least one of the spaces 40

incorporated in the side petals 46 and/or rear petal 16 such that compressing the petals inward using the guidewire holds the side petals 46 and the rear petal 16 in a compressed configuration. The guidewire 4 further extends through the oval hole 40 in the leading petal 12, as discussed above. The compressed orientation of the side petals 46 and rear petal 16 enables dilating the opening through the host vessel wall facilitating advancement of the petals of the end-side fitting into the host vessel interior. When the petals of the end-side fitting are completely advanced through the opening, the mechanism (guidewire 4, hypotube, small dilator, or other device) used to maintain the side petals 46 and/or rear petal(s) 16 in a compressed configuration is removed enabling the petals of the fitting to expand towards their preformed configuration. Upon expansion, the petals engage the interior surface of the host vessel. Then a support device, previously discussed, is advanced over the stem or base 14 of the end-side fitting and is secured to maintain the position of the end-side fitting and prevent blood leakage. As shown in Figures 7A to 7D and previously discussed, relief cuts 48 may be incorporated in the end-side fitting to define extensions 50 which minimizes blood leakage and enable configuring the radius of curvature of the petals to maintain the maximum strain during compressing below the 8 percent limit characteristic of memory elastic materials.

As shown in Figures 9A to 9E, a thin wall sheath 54 having a height substantially smaller than the width or length may be used to maintain the side petals 46 and rear petal 16 in a compressed orientation during insertion through an opening into the host vessel 6. A remote extension 56 is attached to a handle (not shown) and permits remote manipulation of the thin wall sheath 54. As shown in Figures 9D and 9E, the interior surface of the thin wall sheath 54 matches the shape of the distal end of the compressed end-side fitting and provides an opening for the base or stem 14 of the fitting to emerge. The thin wall sheath resembles a dilator in that it provides a smooth surface and transition to expand the opening into the host vessel. The thin wall sheath provides at least one slot 58 on the top 60 of the sheath and at least one slot 62 on the bottom 64 of the sheath which permit separation of the thin wall sheath, once deployed, so the thin wall sheath 54

may be removed from around the compressed end-side fitting. The thin wall sheath 54 also has a minimal wall thickness to facilitate separation of the distal end of the thin wall sheath along the top slots 58 and bottom slots 62. Also, other mechanisms may be used for splittable sheaths that hold the sheath in an intact configuration yet permit separation along the at least one side may be incorporated in top and bottom slots of this thin wall sheath 54 to enable remote separation of the thin wall sheath from around the end-side fitting. Removal of the thin wall sheath 54 allows the side petals 46 and the rear petal 16 to return towards their resting configuration such that the side petals 46 and rear petal 16 engage the interior surface and secure the end-side fitting 2 (thus the attached bypass graft 22) to the host vessel 6.

The petals in many of these fitting embodiments are shown straight (i.e. at an angle of approximately zero degrees from the base of the fitting). During manufacture, the petals may be thermally formed at any angle between about 30 degrees and about 150 degrees from the base of the fitting such that the petals contact the interior surface of the host vessel once the fitting is inserted through the host vessel wall. The petals, having an angle between about 30 degrees and about 150 degrees from the base of the fitting in their resting orientation, also compress into a reduced outer diameter during deployment through delivery system and expand towards their resting configuration once deployed inside the host vessel. The number of petals incorporated in the end-side fitting design depends on the size of the bypass graft and the size of the host vessel. The number of petals also depends on the desired tensile strength between the fitting and the host vessel; increasing the number of petals in turn increases the force required to pull the fitting petals out of the host vessel. After advancing the fitting through an opening into the host vessel wall, the bypass graft and fitting combination is gently retracted to engage the interior vessel wall with the petals. For mechanical securing, a support device is advanced over and locked to the fitting thereby compressing the vessel wall against the petals.

CLAIMS

We claim:

1. An end-side anastomosis system including a fitting comprising:

a base for attachment to a graft, said base being configured to form a seal with an opening in a host vessel wall;

a leading petal having a cross-section with a radius of curvature approximating a radius of curvature of the host vessel, said leading petal being configured to dilate the host vessel wall opening while advancing said fitting through the opening; and

a rear petal, said rear petal being deflectable to be advanced through the host vessel opening.

2. The system of claim 1, wherein said rear petal of said fitting is deflectable toward said base.

3. The system of claim 1, wherein said rear petal has a length such that said fitting can be advanced through the host vessel opening without said leading petal or said base deforming a posterior surface of the host vessel upon introduction of said fitting into the host vessel.

4. The system of claim 1, wherein said fitting defines proximal and distal openings configured to receive a guidewire.

5. The system of claim 1, further including a guidewire.

6. The system of claim 1, wherein said base of said fitting includes a locking mechanism to secure a support device.

7. The system of claim 6, wherein said locking mechanism is selected from a group consisting of tabs and threads.

8. The system of claim 1, further including a support device configured for attachment to said base of said fitting.

9. The system of claim 8, wherein said support device includes a funneled section to relieve stress on the graft.

10. The system of claim 8, wherein said support device has a curved proximal end.

11. The system of claim 8, wherein said support device comprises a slotted member having edges.

12. The system of claim 11, wherein said support device includes a latching mechanism to lock said edges together.

13. The system of claim 11, further including a clip to secure said support device to said base of said fitting.

14. The system of claim 11, wherein said support device includes a flared distal end.

15. The system of claim 8, wherein said support device includes a curved distal end having a curvature generally matching that of the host vessel.

16. The system of claim 1, wherein said fitting includes links defining spaces throughout said leading petal.

17. The system of claim 1, wherein said rear petal is deflectable toward said leading petal.

18. The system of claim 1, wherein said rear petal comprises a separate component from a portion of said fitting including said base and said leading petal.

19. The system of claim 18, wherein said base includes a slot for receiving said separate rear petal.

20. The system of claim 18, wherein said separate rear petal includes a locking mechanism for attachment of said separate rear petal to said base.

21. The system of claim 20, wherein said locking mechanism includes a hooked portion.

22. The system of claim 1, wherein said fitting includes side petals between said leading petal and said rear petal.

23. The system of claim 1 or 22, wherein said petals of said fitting include holes for improved flexibility.

24. The system of claim 1, wherein said fitting includes extensions around said base to provide improved hemostasis.

25. The system of claim 1, further including a deployment sheath for housing said fitting when compressed, said sheath being configured to serve as a dilator and being adapted for removal from said fitting once said fitting is in place.

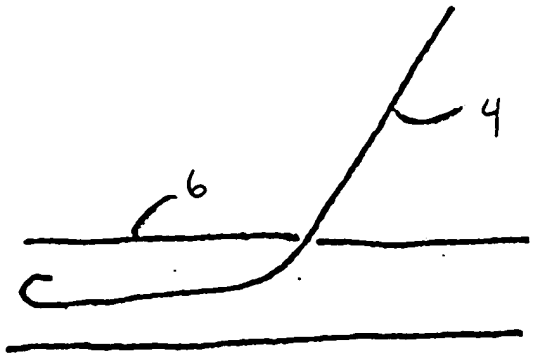


Figure 1A

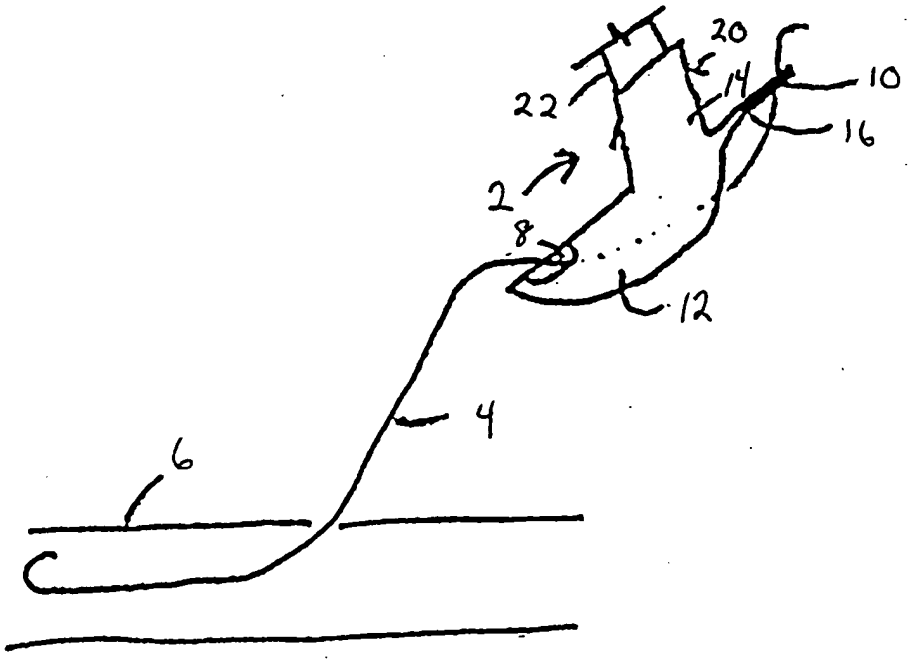


Figure 1B

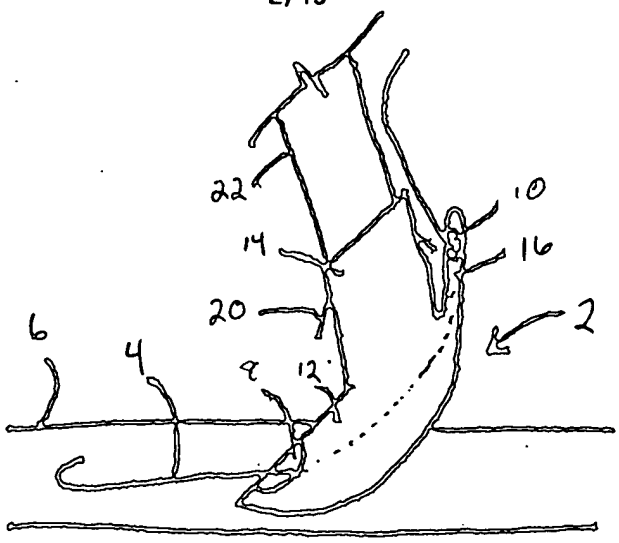


Figure 1C

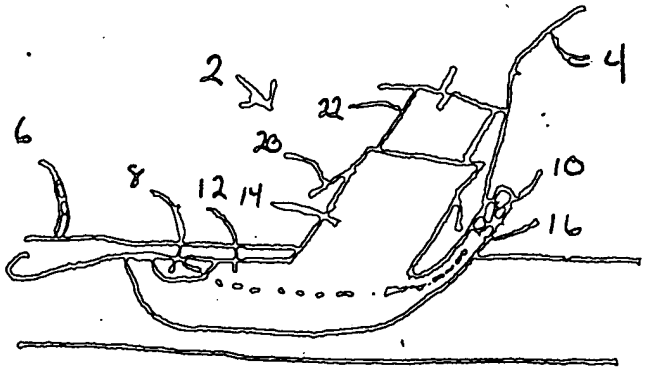


Figure 1D

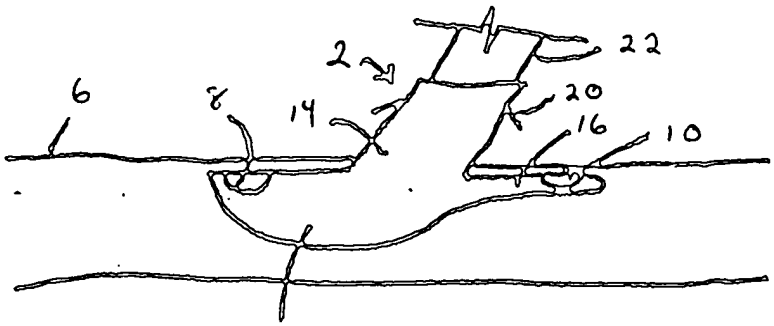


Figure 1 E

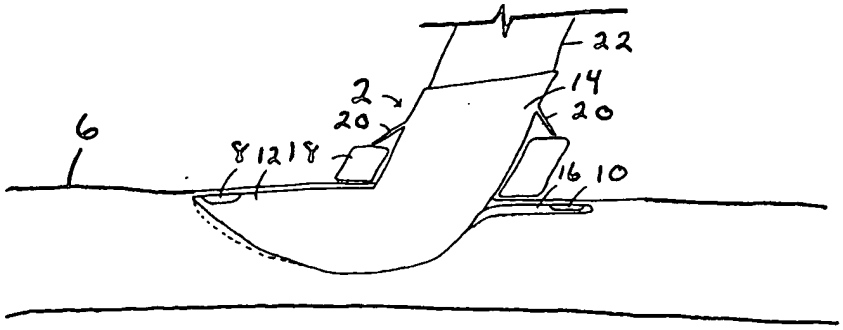


Figure 1 F

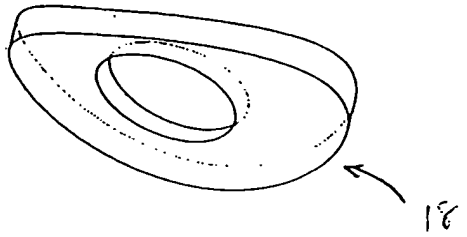


Figure 2A

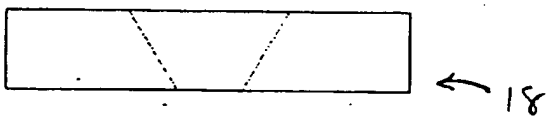
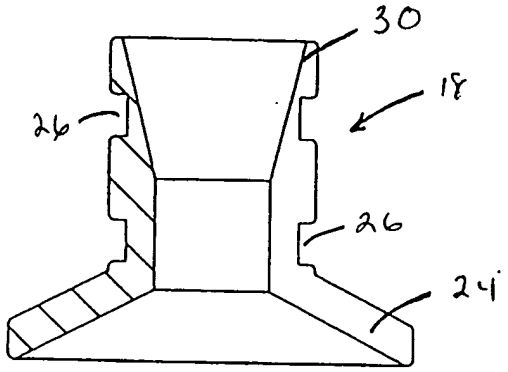


Figure 2B

Figure 2C



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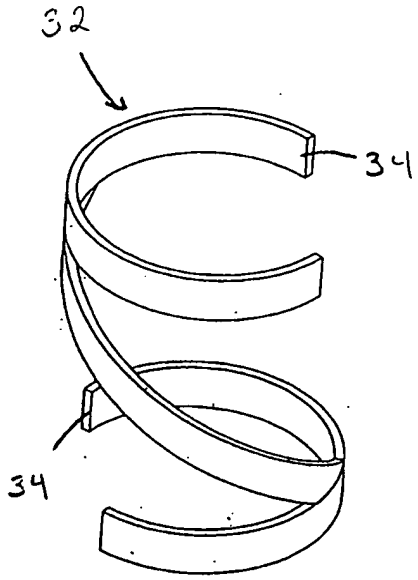


Figure 3C

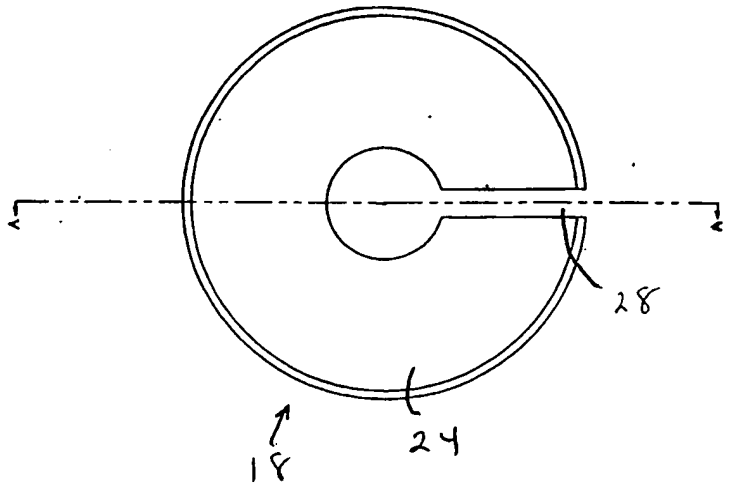


Figure 3B

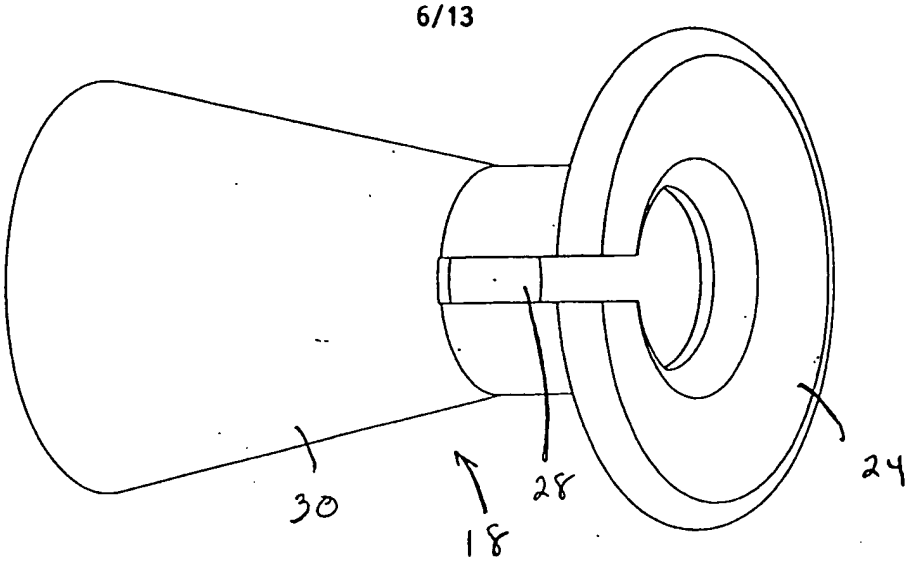


Figure 4

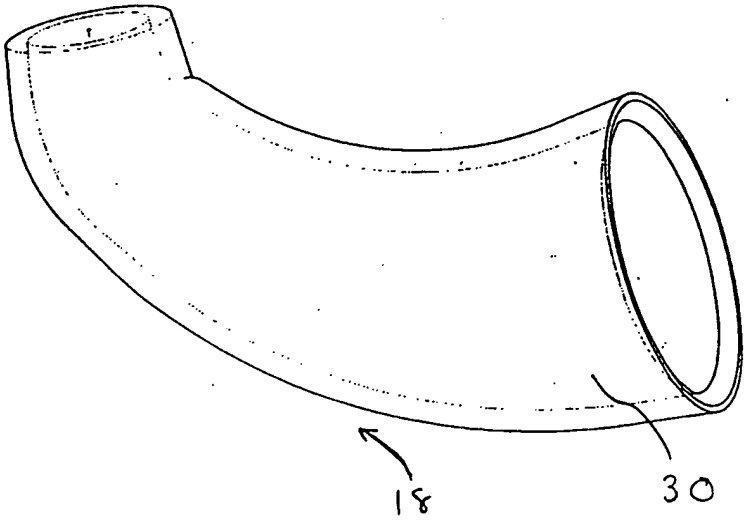


Figure 5

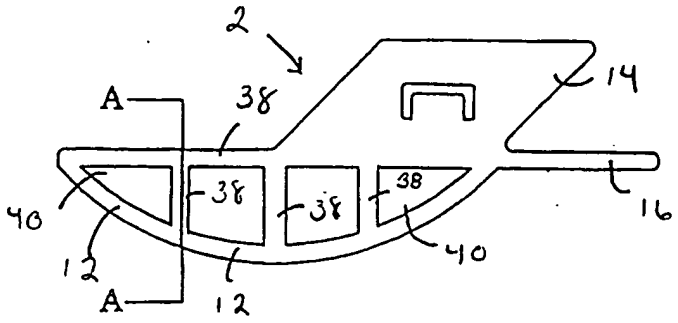


Figure 6A

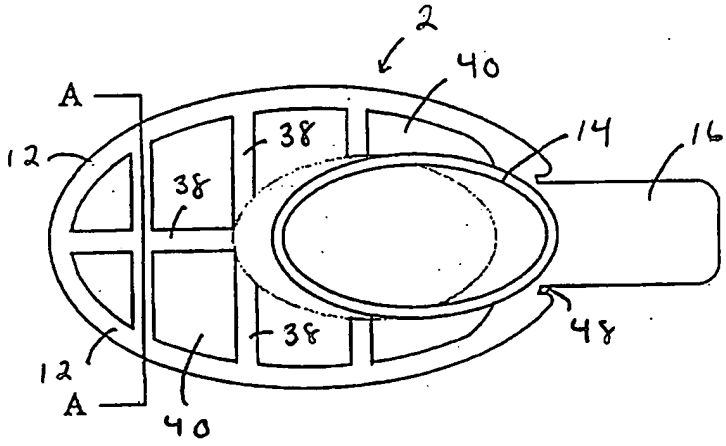


Figure 6B

Figure 6C

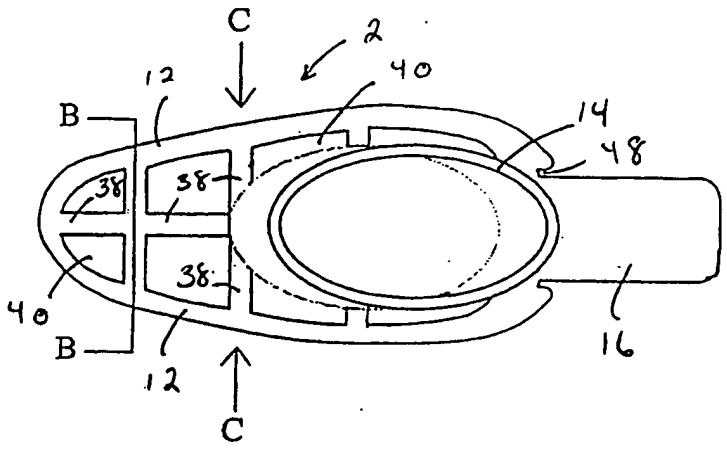


Figure 6D

Figure 6E

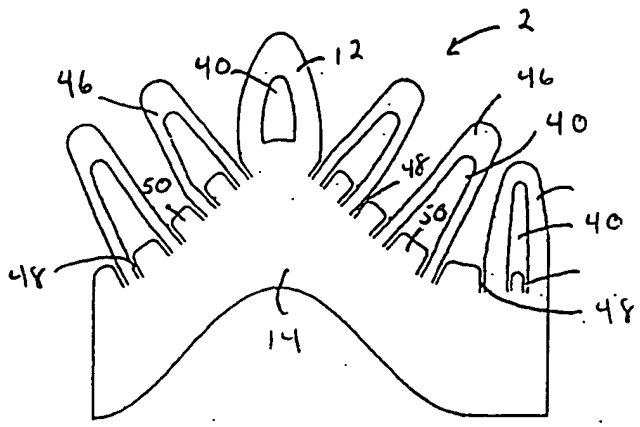


Figure 7A

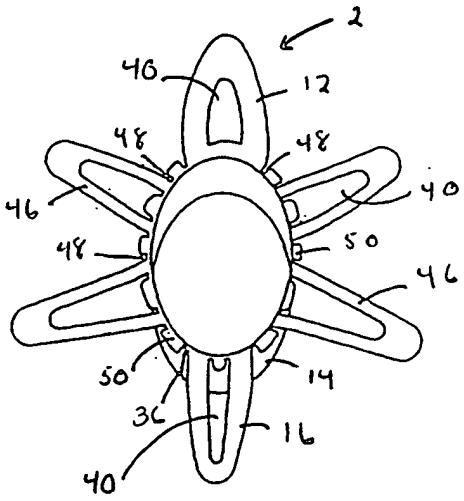


Figure 7B

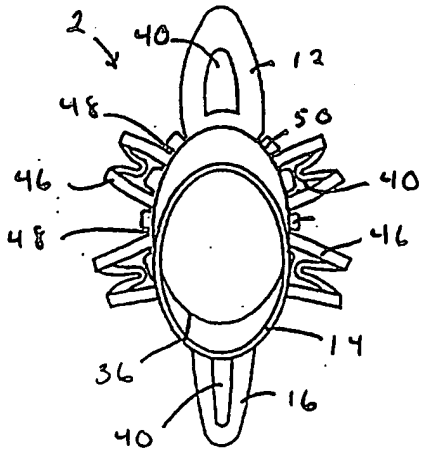


Figure 7C

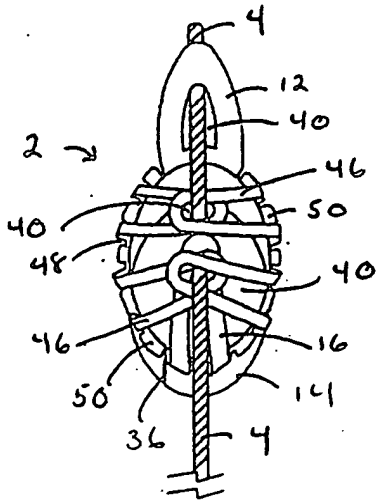


Figure 7D

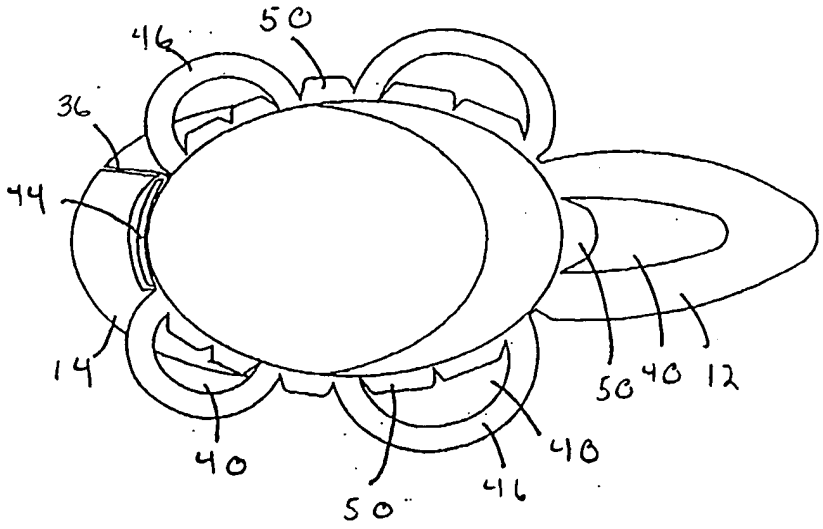


Figure 8A

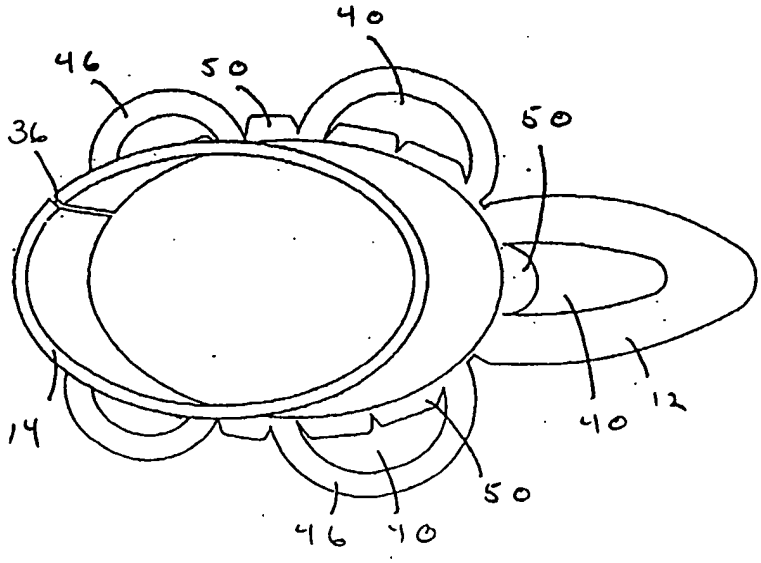


Figure 8B

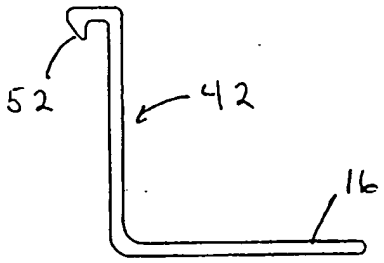


Figure 8C

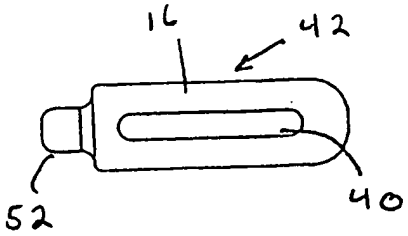


Figure 8D

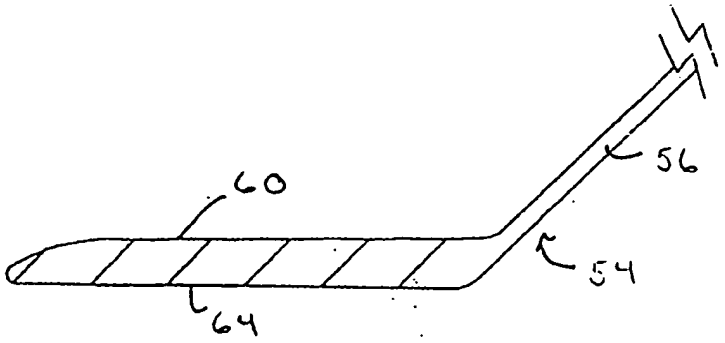


Figure 9A

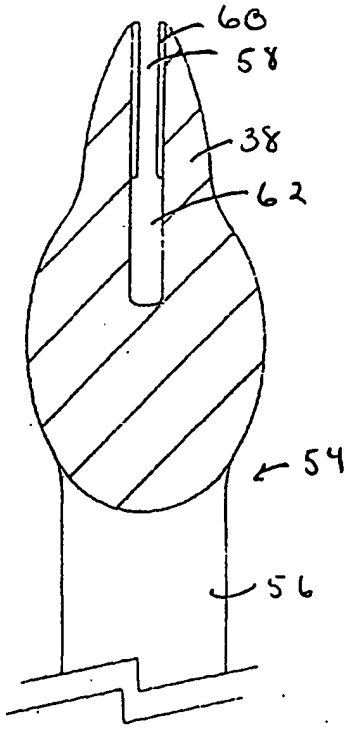
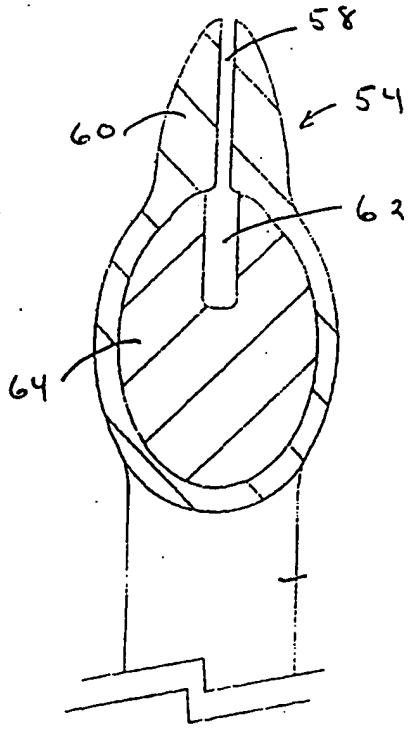


Figure 9B



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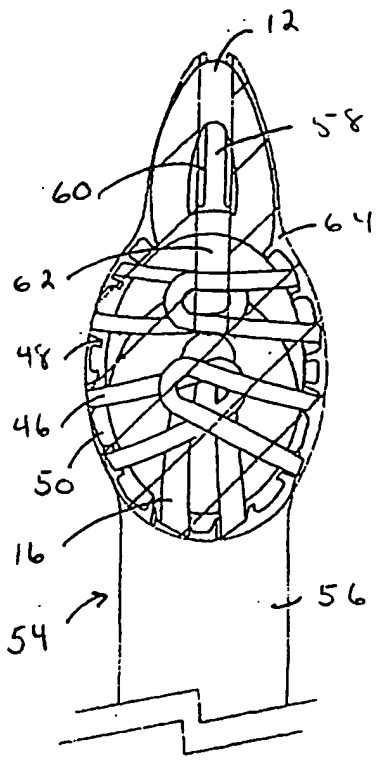

Figure 9D

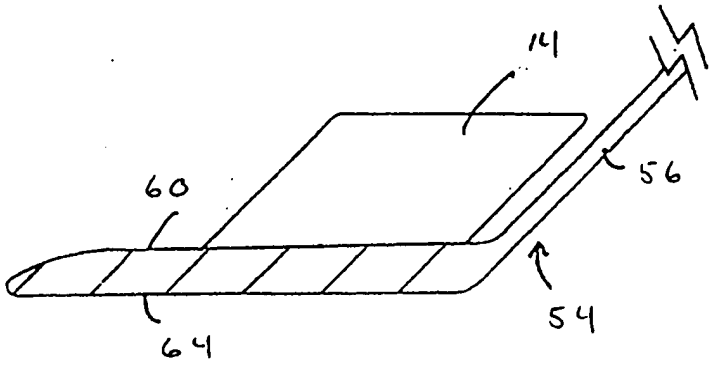

Figure 9E

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14 June 2001 (14.06.2001)

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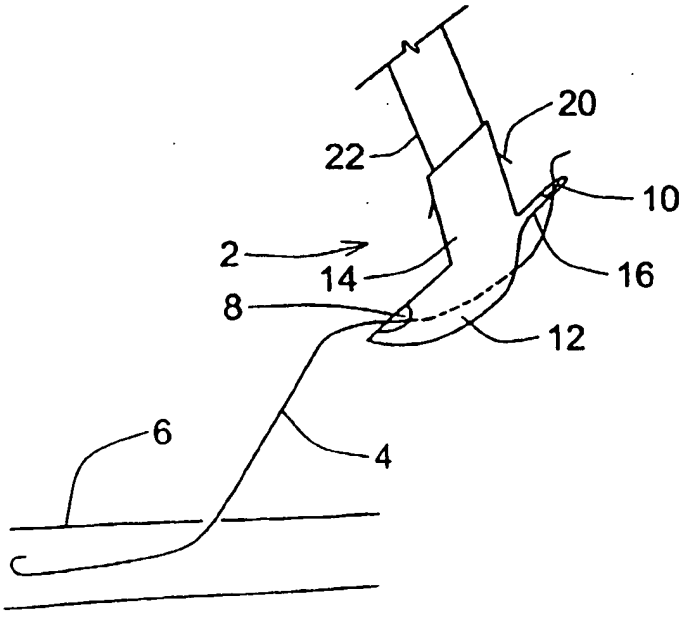
(84) Designated States *(regional)*: European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE, TR).

Published:
— *with international search report*

(88) Date of publication of the international search report:
21 February 2002

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

(54) Title: END-SIDE ANASTOMOSIS SYSTEMS



(57) Abstract: End-side anastomosis fittings are described herein. The fittings may be deployed over a guidewire, in a sheath or by applying side-to-side force and feeding the fitting through an opening in a host vessel wall. When a fitting as described is deployed within a host vessel, the exterior surface of the leading petal contacts the interior surface of the host vessel. A deflectable rear petal anchors the fitting within the host vessel once it is advanced through the host vessel wall. Additional petals that may be included provide more complete contact. Support devices usable with the fittings secure a fitting to a host vessel and prevent blood leakage between the opening through the host vessel wall and the base of the end-side fitting. The support device selected may include funnel features designed to relieve stress on a graft attached to the fitting.

WO 01/41653 A3

INTERNATIONAL SEARCH REPORT

Interna al Application No
PCT/US 00/42569

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61B17/11 A61F2/06

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 7 A61B A61F

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)
EPO-Internal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	EP 0 824 901 A (MUDR MILAN KRAJICEK CSC) 25 February 1998 (1998-02-25) abstract; figures 1,6,9	1-3
X	EP 0 894 475 A (MEDTRONIC INC) 3 February 1999 (1999-02-03) abstract; figure 3	1-3
X	WO 99 48427 A (ROY SUMIT ;FOSSE ERIK (NO)) 30 September 1999 (1999-09-30) abstract; figure 1	1-3
A	WO 98 52474 A (KENSEY NASH CORP) 26 November 1998 (1998-11-26) page 18, line 29 -page 29, line 27; figures 14-30	1-25

-/--

[X] Further documents are listed in the continuation of box C.

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Date of the actual completion of the international search	Date of mailing of the international search report
12 October 2001	22/10/2001

Name and mailing address of the ISA	Authorized officer
European Patent Office, P.B 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax: (+31-70) 340-3016	Hansen, S

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INTERNATIONAL SEARCH REPORT

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PCT/US 00/42569

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication,where appropriate, of the relevant passages	Relevant to claim No.
A	WO 98 40036 A (UNITED STATES SURGICAL CORP) 17 September 1998 (1998-09-17) the whole document	1-25

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Information on patent family members

Interna... al Application No
PCT/US 00/42569

Patent document cited in search report		Publication date	Patent family member(s)		Publication date
EP 0824901	A	25-02-1998	CZ	9602461 A3	18-03-1998
			EP	0824901 A2	25-02-1998
			JP	10075969 A	24-03-1998
			US	5968089 A	19-10-1999
EP 0894475	A	03-02-1999	EP	0894475 A1	03-02-1999
			AU	8650498 A	08-03-1999
			EP	0895753 A1	10-02-1999
			EP	0999790 A1	17-05-2000
			WO	9908603 A1	25-02-1999
WO 9948427	A	30-09-1999	AU	3631099 A	18-10-1999
			EP	1063923 A1	03-01-2001
			WO	9948427 A1	30-09-1999
			NO	20004689 A	20-11-2000
WO 9852474	A	26-11-1998	US	6056762 A	02-05-2000
			AU	7250098 A	11-12-1998
			EP	0983025 A1	08-03-2000
			WO	9852474 A1	26-11-1998
			US	6030395 A	29-02-2000
			US	6036705 A	14-03-2000
WO 9840036	A	17-09-1998	AU	6703298 A	29-09-1998
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